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Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
5630 Fishers Lane, Room 1061 (HFA-305)
Rockville, MD 20852

Dear Sir or Madam:

On behalf of the Association for Professionals in Infection Control and Epidemiology (APIC), I thank you for this opportunity to respond to FDA's draft Guidance for Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals. This is an important issue and we look forward to working with the FDA as the agency considers regulation in this area. We offer the following comment with regard to this issue and to the agency's proposed guidance.

The Association for Professionals in Infection Control and Epidemiology (APIC) is a nonprofit professional organization representing some 12,000 members. APIC's membership is comprised of nurses, medical technologists, microbiologists, epidemiologists, physicians and other health care personnel whose primary responsibility within their facilities is infection prevention and control.

APIC has long been both a patient and employee advocate throughout its 28-year history. Our emphasis is on surveillance, prevention and control of nosocomial infections, science-based practice, policy and procedures, and outcome monitoring and performance measurement.

In recent years, APIC has submitted formal written comment to the FDA, regarding the regulation of reprocessed single-use devices. We still believe there is a need to regulate reprocessors, however, there is also a need for further clarification of the current standards and review processes. APIC recommends enforcement of existing Quality System Regulations and Good Manufacturing Guidelines for both OEMs and reprocessors. This enforcement would increase public safety immediately and provide time for evaluation and development of any additional regulations for assuring safety of reprocessed single-use critical items.

Although critical, semi-critical and non-critical devices are currently being reprocessed with minimal FDA oversight, APIC believes that stricter regulation is necessary *only for critical devices*. Critical devices have a significantly higher level of

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risk associated with their reuse than do non-critical or semi-critical devices. For this reason, health care providers and consumers must be assured that a reprocessed critical device offers the same structural and mechanical soundness as the original device.

While we commend the FDA's intentions to better protect the public health, we believe that FDA's proposal at this point in time is unclear in some areas (with regard to inconsistency in device categorization) and oversimplified in others. Furthermore, we found it too overwhelming to fully understand and consider for direct application. The requirements and compliance issues are too broad and complicated to be assumed by those affected by the policy.

The timeline for compliance (6-months for high risk, 12 months for moderate, and 18 months for low) is insufficient, given the breadth of information that must be understood and addressed within this proposal. Hospitals simply do not have the necessary departments, knowledge and resources to carry out this mandate.

We sincerely hope that FDA will consider regulating only those devices deemed to be of high risk and eliminate moderate and low risk devices from these proposed regulatory requirements. Low and moderate risk devices can be granted necessary oversight using professional standards that are already in place in many facilities. APIC supports stricter regulation for critical items only, (*i.e.*, items that come into contact with sterile tissue and/or the vascular system). Criteria for determining the complexity of reprocessing could include: the presence of a lumen; length and size of the lumen; fine motor mechanisms; structure of the device (such as the presence of joints); the tenacity of the material; the effect of the cleaning and sterilization processes on the materials; and the type of material. High-risk devices should be categorized based on this critical information.

We are concerned about the extremely limited resources available to facilities to comply with this proposal, as well as the limited resources within the FDA to enforce its many requirements. If the agency focuses only on critical/high risk devices, it will more effectively protect the public health without overburdening all affected parties.

APIC has serious concerns that there will be no outside oversight imposed on out-of-hospital reprocessing sites such as freestanding centers, clinics, and physician offices. If the FDA considers reprocessing dangerous enough to warrant regulation, then all reprocessing settings should be regulated equally. We urge FDA to include other sites under any regulation that may ensue.

APIC is pleased to see that some of its suggestions were incorporated into the current working document, such as the use of Spaulding classification and risk assessment methodology. APIC commends the FDA for narrowing its scope to exclude permanently implantable pacemakers as well as opened and unused devices. We do have an overall concern, however, that this proposal is far too onerous and overreaching. We also have noted some seeming oversights and inconsistencies in the categorization of similar devices.

For example, oral and nasal, as well as urethral catheters are classed as low risk - yet APIC questions how these devices could possibly be cleaned effectively. Also, carpal tunnel blades are classified as moderate risk, when other devices of a similar ilk are classified as low risk. Similarly, dental burrs are classified as moderate risk, whereas surgery burrs are classified as low risk. APIC contends that burrs, bits and shavers should not be reprocessed by hospitals, since they do not have adequate methods for measuring the tenacity of the metal or proper technologies for sharpening these devices. Third party reprocessors who are capable of measuring these parameters should do this reprocessing.

APIC agrees with allowing reprocessors the option of declaring conformity to a recognized standard. APIC's guideline on Cleaning, Disinfection and Sterilization is science-based and would serve as an excellent resource in this process. APIC believes that FDA, in conjunction with other agencies, must monitor compliance to these standards. By having established standards, hospitals would then be able to continue reprocessing some SUDs and could contract with a third-party reprocessor for specific items that fall outside their capability or expertise.

APIC also supports the development of consensus standards for the reuse, reprocessing and resterilization of SUDs. Professional and medical societies such as APIC, the Association of periOperative Registered Nurses (AORN), American Society for Microbiology (ASM), Association for the Advancement of Medical Instrumentation (AAMI), American College of Cardiology, American Society for Gastroenterology, American College of Surgeons, Surgical Infection Society, and American Academy of Orthopedic Surgeons would provide valuable clinical insight and expertise into this widespread practice.

APIC has expressed environmental concerns in its recent position paper on biomedical waste, and encourages the evaluation and use of alternatives to disposables, in order to decrease the dioxin build-up associated with plastics. This continues to be of tremendous concern to our organization and we hope that the FDA will consider the impact of this proposal on the environment.

APIC offers the following comments on specific areas of the proposal:

Under **Medical Device Reporting** (page 7), it is important to note that hospitals currently are required to report adverse device-related events. If also required to register as a manufacturer, they will be forced to conduct two levels of reporting. If FDA insists on expanding hospital reporting requirements to mimic those required of manufacturers, we urge that these additional requirements apply only to the SUDs that are reprocessed. As the proposal is now written, it is unclear whether the change in reporting status would also necessitate adherence to additional reporting requirements across the board.

Under **Medical Device Tracking** (page 7), more clarification is needed with regard to the circumstances necessary for such tracking. If a hospital has its own system for tracking, then this provision is not necessary. If, however, a manufacturer distributes

to hundreds of hospitals, this requirement may be necessary, based on what is currently in place through the QSR.

Under **Medical Device Corrections and Removals** (page 8), as currently written any device manufacturer must report device corrections or removals. The premise behind this requirement is not clear to us. Would this apply in the case of a recall? Would it apply if making a slight alteration in the device (or in the actual process)? Without clarification, we cannot comment on the ramifications of this specific requirement.

Under **Quality System Regulation** (page 8), hospitals remain unclear about how to comply with the QSR. This is not surprising, considering the FDA publicly admitted that the agency itself is not clear on its requirements. In general, we find that the classes of devices do not directly relate to the risk categories. Furthermore, the Quality System requirements are different, depending on the class of the device in question.

Under **Premarket Requirements** (page 9), FDA uses very technical regulatory language that may be familiar to manufacturers, but will be largely arcane to hospitals. The requirements under these various scenarios are unclear to us. In some cases low risk devices may require a premarket approval (PMA); in some cases a high-risk device may only require premarket notification (PMN). Furthermore, we are concerned that original device manufacturers may deem certain noncritical features as "essential" which may prevent reprocessors from being able to attain similar FDA approval. If 510 (k) applications are required, as proposed, hospitals will not be able to reprocess, period, and reprocessing will not remain a viable economic alternative.

Under **E** of this same section, FDA proposes a requirement for a "satisfactory inspection of the manufacturing facilities before a PMA may be approved." APIC questions whether FDA, and other agencies as mentioned, have the staff required for such an undertaking. In this case, and throughout this document, the FDA refers readers to Web sites to seek information pertaining to the issue at hand. These referrals for more information add frustration and complexity to an already perplexing document.

Under **F** of this same section, FDA proposes to "take immediate enforcement action for failure to comply with premarket requirements upon determining a 510(k) submission or PMA application is administratively incomplete." This seems far too punitive in nature. Is the goal to inhibit submissions in the first place?

Under **Enforcement Discretion** (page 14), if FDA intends to follow through with these proposals, we need further clarification on how to comply.

We applaud the FDA on its revised reprocessing scheme, particularly the utilization of Spaulding's criteria. We have identified a few areas, however, that still need to be addressed. The categorization and prioritization remains inconsistent, despite agency attempts. Risk categorization that combines/modifies the proposed stratification with current professional recommendations would enhance the applicability of this methodology. FDA has oversimplified this very complex issue by creating three separate

categories for the placement of devices. We may, in fact have devices that fit into different categories, if we properly risk-adjust.

Under **Question 2 on page 5**, we also question whether there actually are compelling data to suggest "reason for concern" in the use of reprocessed devices.

From a hospital perspective, it appears that the intended purpose is to discourage reprocessing altogether. A typical hospital can save upwards of $100,000 by reprocessing just a single type of device. This is significant in today's health care system, where facilities provide a fair share of charity care to indigent populations. Where will the money for indigent care come from, if reprocessing is no longer a viable alternative? Once again, we urge the FDA to concentrate its involvement only on high-risk devices. Otherwise, this becomes an unfunded mandate that is unwieldy in nature and most likely will not impact significantly the occurrence of adverse events.

Infection control professionals are key in helping to establish and evaluate policies, procedures and regulations for reprocessing. APIC looks forward to working with industry, FDA, AAMI, and other professional organizations to gain answers to the many questions surrounding the reuse of disposable devices, and to develop collaborative standards that allow prudent use of both economic and ecological resources while assuring positive outcomes for our patients.

Thank you for the opportunity to comment on this issue. If you have questions or require further information, please contact Jennifer Thomas, APIC Director of Government and Public Affairs, at 202-789-1890 or jthomas@apic.org.

Sincerely,

Susan M. Slavish

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2000 APIC President